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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/566,428	05/01/2006	Pascale Hubert	P71040US0	5761
136	7590	01/09/2008	EXAMINER	
JACOBSON HOLMAN PLLC			WOODWARD, CHERIE MICHELLE	
400 SEVENTH STREET N.W.			ART UNIT	PAPER NUMBER
SUITE 600				1647
WASHINGTON, DC 20004			MAIL DATE	DELIVERY MODE
			01/09/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/566,428	<b>Applicant(s)</b> HUBERT ET AL.
	<b>Examiner</b> CHERIE M. WOODWARD	<b>Art Unit</b> 1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 31 January 2006.  
 2a) This action is FINAL.      2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-9 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-9 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 31 January 2006 is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO-166/08)  
     Paper No./Mail Date 2/7/2007.

4) Interview Summary (PTO-413)  
     Paper No./Mail Date. \_\_\_\_\_

5) Notice of Informal Patent Application

6) Other: \_\_\_\_\_

#### **DETAILED ACTION**

1. Applicant's submission and preliminary amendments, filed 31 January 2006, are acknowledged. Claims 1-9 are pending and under examination.

#### ***Information Disclosure Statement***

2. The information disclosure statement (IDS) submitted on 7 February 2007 has been considered by the examiner. A signed copy is attached hereto.

#### ***Claim Objections***

3. Claim 9 is objected to because of the following informalities: the article "A" is the appropriate article to use in the preamble of the claim. Claim 9 is the only stated method claim in the case, thus, the recitation of "A method..." is appropriate. If claim 8 is amended to recite a method, then the article identifier for claim 9 will be correct and the article of claim 8 should be recited as "A." If, however, claim 8 is amended to a composition claim, the appropriate article of claim 9 will be "A." The article "the" is typically used in dependent claims. Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 101***

4. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claim 8 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966). This rejection may be overcome by amending the claim to recite a method with applicable method steps.

#### ***Claim Rejections - 35 USC § 112, Second Paragraph***

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:  
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 8 provides for the use of a composition according to claim 1, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced. This rejection may be overcome by amending the claim to recite a method with applicable method steps.

***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(c) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 1-4 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Ferrari et al., US Patent 6,355,270 (12 March 2002).

The claims are drawn to a mucoadhesive pharmaceutical composition comprising an acrylic acid containing polymer and a chemoattractant wherein the pH of the composition is at least 6 or less; A method of treating an anogenital or oral disease comprising administering a medically effective amount of the composition of claim 1 to a patient in need thereof.

The '270 patent teaches mucoadhesive agents and bio-polymeric compositions comprising GM-CSF (column 1, lines 58-66; claims 1 and 2) (compare instant claims 1 and 2). Acrylic acid containing polymers are taught at column 6, lines 6-9 (compare instant claim 1). Claim 15 of the '270 patent teaches the pH of the composition at 6.0 (compare instant claim 1). Polycarbophil is taught at Table 1 (compare instant claim 3). Hydrogels are taught at column 1, line 31 (compare instant claim 4).

It is noted that claim 7 recites the composition of claim 1 and an intended use. A composition claim with an intended use is not further limiting where the art anticipates the composition (see *In re Sinex*, 309 F.2d 488, 492, 135 USPQ 302, 305 (CCPA 1962) (statement of intended use in an apparatus claim did not distinguish over the prior art apparatus)).

10. Claims 1 and 3-7, and 9 are rejected under 35 U.S.C. 102(a/e) as being anticipated by Thormar et al., US Patent 6,596,763 (22 July 2003, benefit to 16 December 1999). It is noted that this reference is applied as a prior art reference under 102(a) from the date of issue (22 July 2003) and under 102(e) from the benefit date of 16 December 1999.

The claims recite as stated above. The '763 patent teaches biocompatible compositions comprising acrylic polymers, such as polyacrylic acids and polymethacrylates (column 6, lines 25-26; claim 1 and 22) (compare instant claim 1). Figure 3 teaches the composition at a pH of 4.0, 5.0, and 6.0 (compare instant claims 1, 5, and 6) Suitable agents in the composition which counteract the adsorption of virus to cells are chemokines (14, lines 41-48) (compare claim 1). The pH of the composition Polycarbophil is taught at column 6, line 40 (see also, claim 23) (compare instant claim 3). The '763 patent teaches formulations comprising polymers in the form of hydrogels (abstract; column 4, line 11; claims 1, 22, 23 and 32) (compare instant claim 4). Treatment of the genital mucosa is taught at column 5, line 19 (see also, claim 96) (compare instant claims 7 and 9). Formulations for treating mucosal infections are taught throughout (abstract; claim 96) (compare instant claim 9)

It is noted that claim 7 recites the composition of claim 1 and an intended use. A composition claim with an intended use is not further limiting where the art anticipates the composition (see *In re Sinex*, 309 F.2d 488, 492, 135 USPQ 302, 305 (CCPA 1962) (statement of intended use in an apparatus claim did not distinguish over the prior art apparatus). In the instant case, the composition of claim 1 is capable of performing the intended use as a treatment (see the '763 patent, column 5, line 19).

### ***Conclusion***

NO CLAIM IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHERIE M. WOODWARD whose telephone number is (571)272-3329. The examiner can normally be reached on Monday - Friday 9:00am-5:30pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1647

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cherie M. Woodward/  
Examiner, Art Unit 1647